K011057

JUN - 6 2001

PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.92)

807.92 (a):

1. *Submitter's Name:* OraSure Technologies, Inc.
   Address: 150 Webster St., Bethlehem, PA 18015
   Telephone Number: (610) 882-1820
   Contact Person: R. Sam Niedbala, Ph.D., BCFE
   Date Prepared: March 30, 2001

2. *Device Name:*
   Proprietary Name: Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device
   Usual Name: Intercept™ Oral Specimen Collection Device
   Classification Name: Blood Specimen Collection Device

3. *Device to Which Substantial Equivalence Is Claimed:*
   OraSure® Oral Specimen Collection Device; K970357

4. *Description of Device:*
   The Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device consists of a treated absorbent cotton fiber pad affixed to a nylon stick (Collection Pad) and a preservative solution in a plastic container (Specimen Vial). The Collection Pad is impregnated with a mixture of common salts and gelatin, creating a hypertonic environment which produces an osmotic gradient across the buccal and gingival mucosae. The Pad is placed in contact with the gingival mucosa (between the lower cheek and gum) which enhances the flow of mucosal transudate onto the absorptive cotton fibers of the Pad. Following the collection period, the Collection Pad is removed from the mouth and placed into a Specimen Vial. The vial contains a preservative solution which serves to inhibit the growth of oral microorganisms recovered on the Collection Pad. The vial is sealed with a plastic cap and transported to a laboratory for processing and testing.

5. *Intended Use Statement:*
   The Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device is intended for use in the collection, preservation, and transport of oral specimens. Oral specimens collected with the Intercept™ Oral Specimen Collection Device can be used to detect cocaine and cocaine metabolites, cannabinoids, phencyclidine, amphetamine, methamphetamine, opiates, barbiturates and methadone with the OraSure Technologies Intercept™ MICRO-PLATE EIAs.

6. *Comparison of Technological Characteristics:*
   The Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device is substantially equivalent to the OraSure® Oral Specimen Collection Device, K970357. Both devices share the same major components (collection apparatus and transport container containing a preservative solution) and are intended for collecting an oral fluid specimen, and for containing and transporting that specimen. The oral specimens collected with the Intercept™ device, however, can be used to detect cocaine and cocaine metabolites, cannabinoids, phencyclidine, amphetamine, methamphetamine, opiates, barbiturates and methadone with the OraSure Technologies Intercept™ MICRO-PLATE EIAs as demonstrated in the premarket notifications for the assays (K001197, K000399, K992918, K002375, K993208, K981341, K001976, K002010). OraSure Technologies considers this device to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 6 2001

R. Sam Niedbala, Ph.D., BCFE
Chief Science Officer
OraSure Technologies, Inc.
150 Webster Street
Bethlehem, PA 18015-1389

Re: 510(k) Number: K011057
Trade/Device Name: Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device
Regulation Number: 862.1675
Regulatory Class: II
Product Code: JKA
Dated: March 30, 2001
Received: April 6, 2001

Dear Dr. Niedbala:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K011057

Device Name: Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device

Indications For Use:

The Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device is intended for use in the collection, preservation, and transport of oral specimens. Oral specimens collected with the Intercept™ Oral Specimen Collection Device can be used to detect cocaine and cocaine metabolites, cannabinoids, phencyclidine, amphetamine, methamphetamine, opiates, barbiturates and methadone with the OraSure Technologies Intercept™ MICRO-PLATE EIAs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Fred Lacy

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011057

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

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